

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: WAVE 3 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**REPLY MEMORANDUM IN SUPPORT OF SUPPLEMENTAL MOTION TO
EXCLUDE AND NOTICE OF ADOPTION OF PRIOR DAUBERT MOTION AND
REPLY BRIEF OF ABBAS SHOBEIRI, M.D.**

Defendants Ethicon, Inc., Ethicon, LLC and Johnson & Johnson (hereinafter “Ethicon”) submit this reply memorandum in further support of their supplemental motion to exclude certain opinions of Abbas Shobeiri, M.D.

INTRODUCTION

Ethicon has moved, in its supplemental memorandum (Dkt. 2767), for exclusion of Dr. Shobeiri’s opinions regarding the alleged design defects of Ethicon’s TVT-O and Prolift products on the ground that Dr. Shobeiri fails to reliably support his opinion that these products are “more likely than not” the cause of certain injuries, including pain and dyspareunia. (Mem. in Supp. of Defs.’ Supp. Mot. to Exclude and Notice of Adoption of Prior Daubert Mot. and Reply Br. of Abbas Shobeiri, M.D. for Wave 3 (“Defs.’ Mem.”), Dkt. 2767 at 1). In response, instead of focusing on Ethicon’s argument that Dr. Shobeiri fails to explain his reasoning underlying this opinion, Plaintiffs instead focus on Dr. Shobeiri’s opinions on frequency and severity of complications, as well as his opinions on bladder infections. Such arguments miss the point entirely: Dr. Shobeiri opines that, when a woman presents with pain and dyspareunia,

and that woman has a TVT-O or Prolift product, that the mesh product is automatically “more likely than not” the cause of her pain and dyspareunia. His opinion is unsupported, unexplained, and should be excluded.

LEGAL ARGUMENT

As an initial matter, Plaintiffs contend that Ethicon’s motion is somehow a motion for the Court to reconsider its ruling as to Dr. Shobeiri in Wave 1. In its Wave 1 Motion, Ethicon contended that the Court should exclude the following opinions of Dr. Shobeiri: (1) alleged design defects in the TVT-O and Prolift that were not supported by scientific evidence and that he was not qualified to address; (2) safer alternative products whose comparative safety and efficacy had not been quantified; (3) allegedly inadequate warnings that he was not qualified to address; (4) alleged inadequate training and education that is not relevant; and (5) Defendants’ knowledge, state of mind, or intent. (Dkt. 2077 at 2). In its ruling on Ethicon’s Wave 1 Motion, the Court ruled as follows: (1) Dr. Shobeiri’s expert testimony was based on his experience and review of the medical literature and was therefore admissible; (2) Dr. Shobeiri’s testimony on alternative procedures was reserved for ruling at trial; (3) Dr. Shobeiri was qualified to opine on biocompatibility issues; (4) Dr. Shobeiri cited scientific studies in support of his design defect opinions and the opinions were reliable on that basis; (5) Dr. Shobeiri was not qualified to offer opinions on product warnings; and (6) the Court reiterated its rulings on recurring issues, excluding, among other things, any state-of-mind and legal-conclusion expert testimony, as well as any testimony that is solely a conduit for corporate information and documents. (Dkt. 2685).

Plaintiffs seek to characterize Ethicon’s present Motion as one for reconsideration of the Court’s Wave 1 order. (Plaintiffs’ Resp. and Opp’n to Defs.’ Mot. to Exclude Certain Opinions of Abbas Shobeiri, M.D. (“Pls.’ Resp.”), Dkt. 2956, at 2 (“Ethicon now comes before the Court

asking it to reverse itself concerning the admissibility of these design defect opinions.”)). But Ethicon did not file a Motion for Reconsideration. The MDL Court’s pretrial orders expressly contemplate—and indeed *require*—filing a *Daubert* motion with respect to the general-causation experts’ opinions on a wave-by-wave basis.

Under this Court’s Docket Control Orders, Ethicon is limited to filing one *Daubert* motion per general-causation expert with respect to each wave of cases. Indeed, the Docket Control Order for the Wave 3 cases specifically scheduled new *Daubert* deadlines for the 200 cases that are unique to Wave 3. *See* Pretrial Order #239 at 4; *see also* Pretrial Order #210. The two *Daubert* motions already filed in this MDL for Waves 1 and 2 do not apply to the 200 Wave 3 cases. If Ethicon wanted to limit Dr. Shobeiri’s general-causation opinions with respect to these cases, it was required to file a *Daubert* motion or Notice of Adoption as part of Wave 3.

Contrary to Plaintiffs’ assertion that Ethicon has raised “no new reason” for the Court to exclude Dr. Shobeiri’s design defect opinions, the arguments that Ethicon has raised in Wave 3 are tailored to addressing an issue not resolved by the Court’s Wave 1 ruling on Dr. Shobeiri’s opinions. (Pls.’ Resp. at 4-5). Although Ethicon acknowledges that the Court declined to exclude Dr. Shobeiri’s design defect opinions in its Wave 1 ruling because it concluded that Dr. Shobeiri cited to “numerous studies in support of his opinions” (Dkt. 2685 at 7), Ethicon moves to exclude his opinions here for a separate reason *not* considered by the Court in Wave 1. Specifically, this Court in Wave 1 did not address whether these opinions should be excluded because Dr. Shobeiri himself concluded that there are other causes of pain and dyspareunia in women besides TVT-O and Prolift and failed to reconcile that fact with his opinion that TVT-O and Prolift are automatically *more likely than not* the causes of such pain and dyspareunia.

Now that this Court has had an opportunity to decide some of the previously briefed issues, filing a new motion is not only appropriate, but actually fosters efficiency by presenting issues that can be decided prior to trial. Nor is Ethicon precluded from raising new arguments in this motion that were not previously included in the Wave 1 or Wave 2 motions, which did not apply to any of the 200 Wave 3 cases. There is simply no basis—and Plaintiffs have cited no authority—for concluding that motions filed with respect to those previous waves have any waiver or preclusive effect on the Wave 3 cases.

I. Dr. Shobeiri's opinions on design-defect causation are unsupported and inadmissible.

In its Motion, Ethicon moved to exclude Dr. Shobeiri's opinion that, for a woman presenting with pain and dyspareunia following placement of a TVT-O or Prolift device, these symptoms are "more likely than not" associated with the properties, material and/or placement flaws of the TVT-O and Prolift devices. (Defs.' Mem. at 2). Ethicon contended that this opinion was unreliable because Dr. Shobeiri failed to account for the fact that these injuries (pain and dyspareunia) can occur in the absence of the TVT-O or Prolift, and can in fact occur with any vaginal surgery. (*Id.*). When asked specifically to explain his opinion that the TVT-O had an "unacceptably high rate of chronic pain," Dr. Shobeiri failed to cite any scientific studies and circularly reasoned that "you're operating in a space that causes the kind of pain that is hard to get rid of and that's unacceptable" to him." (*Id.*). Given Dr. Shobeiri's complete failure to explain how TVT-O and Prolift's design, materials, and/or placement could automatically be the cause of pain or dyspareunia in women who could have experienced these issues *even if* they had not been implanted with these mesh devices, Ethicon moved the Court to exclude this testimony as unreliable. (*Id.* at 3).

In response, although Plaintiffs accuse Ethicon of failing to cite all of Dr. Shobeiri's testimony, they skirt the issue of *whether or not Dr. Shobeiri actually explains his opinions* and instead attempt to reframe the issue as whether or not Dr. Shobeiri opined that the "injuries caused by mesh are the same as injuries caused by other medical conditions." (Pls.' Resp. at 2). Having set up this straw man distinction, they then cite Dr. Shobeiri's deposition testimony in which he opines that Ethicon's mesh products cause injuries that differ from injuries associated with other types of pelvic surgery in severity, permanence and frequency. (*Id.* at 3).

Plaintiffs miss the point of Ethicon's Motion entirely. Dr. Shobeiri does not explain how frequency and severity are relevant to his opinion that TVT-O and Prolift are automatically "more likely than not" the cause of a woman's pain and dyspareunia following surgery. Further, a quick review of Dr. Shobeiri's testimony on the point of frequency and severity demonstrates that he was asked in deposition to explain the basis for this opinion, and he completely failed to do so. (*See* Ex. 3 to Pls.' Resp., 2/27/16 Deposition of Abbas Shobeiri, M.D. at 81:19-82:9). Plaintiffs also point to Dr. Shobeiri's deposition testimony regarding whether or not bladder infections or urinary tract infections are "more common" with TVT-O than other kinds of mesh, again ignoring the fact that Ethicon's Motion challenges his opinions regarding pain and dyspareunia. (Pls.' Resp. at 3).

In short, Plaintiffs fail to address the relevant opinion challenged and the relevant complications that Dr. Shobeiri states are automatically "more likely than not" caused by TVT-O or Prolift (presumably overriding each individual woman's medical history and unique comorbidities). The testimony that Plaintiffs cite fails to cure the fundamental problem with Dr. Shobeiri's testimony: his utter lack of explanation for why TVT-O and Prolift are always "more likely than not" the cause of a woman's pain and dyspareunia. *See In re Mirena IUD Prod. Liab.*

Litig., 169 F. Supp. 3d 396, 432 (S.D.N.Y. 2016) (holding that expert’s opinion did not meet the requirements of Rule 702 and *Daubert* where “during his deposition he did not explain why the growth of cells in these studies lends support to his theory that presence of an IUD leads to cell growth around it in the uterus”); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 721 (S.D.W. Va. 2014) (excluding opinions on complication rates where “Dr. Blaivas did not explain his methodology and admitted that it was impossible to calculate an accurate complication rate”); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 880, 886 (E.D. Ark. 2008) (overturning punitive damages award based on Dr. Parisian’s testimony in part because she “did not explain the documents, provide summaries, or tie them in to her proposed regulatory testimony” and “did not provide analysis, opinion, or expertise.”). Dr. Shobeiri’s causation opinion suffers from all of these same flaws because he does not explain his methodology. This Court has rejected—not endorsed—this type of flawed methodology and the resultant unreliable opinions, and the Court should do so again here and now.

II. Dr. Shobeiri’s lack of explanation goes to the admissibility of his opinions.

Plaintiffs next contend that the fact that pain and dyspareunia can occur even in the absence of TVT-O or Prolift “goes, at best, to the weight of the opinions and not their admissibility.” (Pls.’ Resp. at 4). This displays a fundamental misunderstanding of Rule 702 of the Federal Rules of Evidence: a witness may testify as an expert only if his or her testimony is “the product of reliable principles and methods.” Fed. R. Evid. 702. In the present case, as demonstrated above, Dr. Shobeiri’s opinion is unreliable because of his failure to explain why TVT-O and Prolift are automatically “more likely than not” the cause of a woman’s pain and dyspareunia. Plaintiffs cite to the Court’s ruling regarding Dr. Ostergard’s testimony in *Hall v. Boston Scientific Corp.*, No. 2:12-cv-08186, 2015 WL 868907, at *23 (S.D. W. Va. Feb. 27,

2015), in support of the proposition that “it is not the Court’s place at the *Daubert* stage to decide the ‘rightness’ of an expert’s conclusions” and that the Court instead should focus on whether the expert’s methodology was sound.” (Pls.’ Resp. at 4). But this only underscore’s Ethicon’s point: if Dr. Shobeiri cannot explain his opinion, his methodology is not reliable. The issue regarding Dr. Ostergard’s opinion in *Hall* was Boston Scientific’s contention that he had misinterpreted the medical articles he relied on in reaching his opinions and that his opinions, therefore, were unreliable. This is not the issue before the Court in the present motion, and *Hall* is inapplicable. Dr. Shobeiri’s proposed testimony is properly before the Court at the *Daubert* stage and should be excluded.

CONCLUSION

Based on the foregoing reasons and the reasons in its memorandum of law, Ethicon respectfully requests the Court grant their Motion to Exclude the Testimony of Abbas Shobeiri, M.D.

Respectfully Submitted,

/s/Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
Christy.jones@butlersnow.com

/s/ David B. Thomas

David B. Thomas (W. Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)

P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND
JOHNSON & JOHNSON

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEMS PRODUCTS LIABILITY
LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

ETHICON WAVE 3 CASES LISTED IN
EXHIBIT A

JOSEPH R. GOODWIN U.S. DISTRICT
JUDGE

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this day I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas

David B. Thomas (W. Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC., ETHICON, LLC AND
JOHNSON & JOHNSON